

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 6, 2020

Ellen M. Baldassare Regulatory Affairs and Product Stewardship Consultant LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner

EPA Registration Number: 39967-138 Application Date: March 17, 2020

Decision Number: 560863

Dear Ms. Baldassare:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, and enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against hepatitis A virus (FRhK-4 cells)(HAV) and feline calicivirus ATCC VR-782 (surrogate for Norwalk virus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: stamped label

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

# Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner

# [Broad Spectrum Disinfectant] [Hospital Disinfectant]

[FOR USE IN: Cleaning and disinfecting hard non-porous surfaces in institutional, commercial, residential and public service facilities including hospitals and nursing homes; field medical units, medical and dental offices; clinics and other health-care facilities; Emergency Medical Services (EMS) facilities, equipment and gear including respirators; laboratories; food processing plants, equipment and warehouses; food service and preparation areas including commercial and institutional kitchens, restaurants and cafeterias; restrooms and portable restrooms; retail stores including supermarkets, florists, barbers, and beauty salons; factories; schools and daycare centers; hotels; offices; correctional facilities; funeral parlors and mortuaries; gymnasiums, stadiums and health spas; transportation terminals and vehicles including ships, automobiles, trucks, trains, and homes and residences.]

[EFFECTIVE AGAINST A WIDE RANGE OF VIRUSES\*, BACTERIA, AND FUNGI:]

[\* Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus), Influenza A Virus, Respiratory Syncytial Virus (RSV), Norovirus (Norwalk-like Viruses), Avian Influenza Virus, [Pandemic 2009 H1N1 influenza A virus].

[Bacillus cereus, Campylobacter jejuni, Chlamydia psittaci, Clostridium perfringens, Listeria monocytogenes, Shigella sonnei, Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli O157:H7, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Methicillin-Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococcus faecalis, (VRE), Candida albicans, and Trichophyton mentagrophytes]

[Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]

[This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.]

[This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]

[Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).]

[Kills Pandemic 2009 H1N1 influenza A virus.]

**ACTIVE INGREDIENTS** 

Potassium peroxymonosulfate 21.41% Sodium chloride 1.50% OTHER INGREDIENTS 77.09% TOTAL 100.00%

[Equivalent to 9.75% Available Chlorine]

# ACCEPTED

04/06/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

39967-138

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

Front Panel Continued

#### KEEP OUT OF REACH OF CHILDREN

## DANGER / PELIGRO

[See [Back Panel] [Box] for Additional Precautions][and product insert for Directions for Use]

[See product insert for [additional precautions and] Directions for Use]

[POWDER FORM]

[TABLET FORM]

#### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### If in Eyes:

Hold eye open and rinse slowly and gently with water for 15-20 minutes.

Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call

a Poison Control Center or doctor for further treatment advice.

#### If on Skin:

Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15-20 minutes.

Call a Poison Control Center or doctor for further treatment advice.

#### If Swallowed:

Call a Poison Control Center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.

Do not induce vomiting unless told to do so by the poison control center or doctor.

Do not give anything by mouth to an unconscious person.

For 24-hour emergency information on this product, call 866-673-6350.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Net Contents: [0.18 oz. (5 grams), 0.35 oz. (10 grams), 1.44 oz. (40 grams), 1.75 oz. (50 grams), 1.1 lbs. (500 grams), 11 lbs. (5 kilograms)] [ See individual product] [refer to container label]

[When dissolved in lukewarm water forms a [16 oz] [32 oz] [1 gallon] [5 quarts] [13 gallons] [132 gallons] 1% solution]

A 1% solution is stable as a broad spectrum disinfectant for 7 days.

[Use one 5 gram tablet in 16 oz of water to make a 1% solution]

[Use two 5 gram tablets in 32 oz of water to make a 1% solution]

[Use one 40 gram tablet in 1 gallon of water to make a 1% solution]

Manufactured for Lanxess Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275 For information: US/Canada (800) LANXESS International +1 412 809 1000

EPA Reg. No.39967-138

EPA Est. No. XXXXX

<Lot or batch #>

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Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

#### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### INSTITUTIONAL, FOOD PROCESSING, AND PUBLIC SERVICE FACILITIES

With Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner, only one product is needed to clean and disinfect.

Do Not Use Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner on acid-sensitive surfaces such as marble or soft metals such as copper, brass, and certain grades of aluminum. Avoid splashing Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution on textiles or carpets. End-user should assure compatibility of all critical materials that may be contacted by Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner.

Do not mix product or in-use solution with other chemicals including bleach or other halogen-containing materials.

Cleaning Procedure: Remove gross dirt and prepare a 1.0% solution according to the table below. Apply to surface using a sponge, brush, or spray device, scrubbing as necessary until the surface is visibly clean. Rinse.

Cleaning and Disinfecting Hard Non-porous Food Contact Surfaces: Remove gross dirt and prepare 1.0% solution according to the table below. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. Let stand for 10 minutes and rinse with potable water.

Cleaning and Disinfecting Hard Non-porous Non-Food Contact Surfaces: Remove gross dirt and use 1.0% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution prepared according to the table below. Apply to surface using a mop, sponge, brushes or spray device until the surface is visibly clean. Let stand 10 minutes and air dry. In cases of fungal contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution.

This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

#### Cleaning and Disinfecting, or Sanitizing Manikins Used in CPR Training:

#### Sanitizing manikins between students:

Prepare a 3% solution of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner [according to dilution chart] [by dissolving 3 tablets (5 gm each) of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner in one pint [16 oz] water] [by dissolving 1 tablet (5 gm) of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner in pre-marked 5.3 oz spray bottle that has been filled to line with water.] Thoroughly spray the manikin surface (mouth and nose area) or wipe with a cloth saturated with 3% solution until fully wetted. Allow surface to remain visibly wet for a minimum of 30 seconds, and wipe with a disposable cloth until dry. Rinse surface with potable water.

#### Cleaning and disinfecting manikins after class:

Manikins should be cleaned as soon as possible at the end of each class to avoid drying of contaminants on surfaces. Disassemble the manikin as directed by the manufacturer's instructions. Thoroughly wash all internal and external surfaces and reusable protective face shields with a brush using a 1% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution. Let stand for 10 minutes and rinse with potable water.

#### **Crisis Scene Disinfection of Hard Non-Porous Surfaces:**

For bacterial and viral\* control: Streptococcus pyogenes, Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus

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aureus, Methicillin-Resistant Staphylococcus aureus (MRSA), Vancomycin-Resistant Enterococcus faecalis, (VRE), and Staphylococcus epidermidis.

\*Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV

(Human Immunodeficiency Virus (HIV-1) (AIDS virus), Influenza A, Respiratory Syncytial Virus (RSV), Norovirus (Norwalk-like viruses), Avian Influenza Virus, [Pandemic 2009 H1N1 influenza A virus].

Not for use with Medical Instruments.

This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

[For [sachet] [pouch] [packet] [bag] packaged with bottle of water: Remove gross dirt. To make a 1% solution, remove cap from bottle of pre-measured water provided. Completely empty entire contents of [sachet] [pouch] [packet] [bag] into the bottle of water provided. Recap bottle and gently shake until powder is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For tablet packaged with [16 oz][32 oz]bottle of water: Remove gross dirt. To make a 1% solution, remove cap from bottle of pre-measured water provided. Add [one][two] tablet(s) into the bottle. Recap bottle and gently shake until tablet is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For [sachet] [pouch] [packet] [bag] packaged with empty bottle: Remove gross dirt. To make a 1% solution, remove cap from empty bottle provided. Fill bottle with water. Completely empty contents of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner [sachet] [pouch] [packet] [bag] into the bottle of water, recap bottle, and gently shake until powder is dissolved. Remove cap and replace with sprayer. Apply to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For tablet packaged with empty [16 oz][32oz]bottle: Remove gross dirt. To make a 1% solution, remove cap from empty bottle provided. Fill bottle with water. Add tablet into the bottle, recap bottle, and gently shake until tablet is dissolved. Remove cap and replace with sprayer. Apply solution to surface until surface is visibly wet. Let stand 10 minutes and air dry.]

[For a 1% solution from powder: Remove gross dirt. Refer to dilution chart. Fill container with required amount of water and add Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner powder to achieve solution concentration. Cap container and gently shake until powder is dissolved. Apply solution to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry.]

[For a 1% solution from tablet: Remove gross dirt. Add one 5 gm (0.18 oz) Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner tablet per pint of water. Cap container and gently shake until tablet is dissolved. Apply solution to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry.]

[To Use for Cleaning and Disinfecting Respirator Face Plates: Disassemble respirator per manufacturer's directions for cleaning and disinfection. Remove gross dirt. Refer to Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner dilution chart. Prepare a 1% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution by fully dissolving the appropriate amount of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner (powder or tablets) in water. Submerge or spray the respirator face plate with a 1% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner solution so that the surfaces to be disinfected remain wet for 10 minutes. Rinse thoroughly with water to remove disinfectant. Allow to dry].

[<u>To Use as an absorbent for blood, body fluids, or vomit:</u> Cover soiled area with Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner powder. Let stand for 10 minutes and scoop into plastic bag and handle as biohazardous waste. Follow up with a disinfectant step by applying a 1% Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner

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solution (prepared according to dilution chart) to surface using a sponge, brush, or spray device until the surface is visibly wet. Let stand for 10 minutes and air dry. Bag containing soil must be disposed of as infectious waste.]

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST \*HIV-1, Hepatitis B (HBV), and Hepatitis C (HCV) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

\*Kills HIV-1, HBV, and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes, etc.) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects using a cleaner (such as Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner) before application of this product as a disinfectant. (See previous label instructions for use of Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner as cleaner.)

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

A 1% solution is effective as a [broad spectrum disinfectant][hospital disinfectant] for 7 days.

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## **DILUTION CHART**

Choose a product option from the list below		Add the following amount of <b>Rely+On™ Multipurpose Disinfectant Cleaner</b> to the designated volume of water					
		1% Use-Diluted Solution					
Rely+On™ Multipurpose Disinfectant Cleaner Product			16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)
Metric	Standard						
5 g Tablet	0.18 oz. Tablet		1 Tablet	2 Tablets	8 Tablets	10 Tablets	40 Tablets
40 g Tablet	1.44 oz. Tablet				1 Tablet		5 Tablets
50 g Sachet	1.8 oz. Sachet					1 Sachet	4 Sachets
500 g Shaker Bottle	17.6 oz. Shaker Bottle		1 tsp.	2 tsp.	8 tsp.	10 tsp.	40 tsp.
5 kg Bucket	176 oz. Bucket		1 tsp.	2 tsp.	8 tsp.	10 tsp.	40 tsp.
		2% Use-Diluted Solution					
Metric	Standard		16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)
5 g Tablet	0.18 oz. Tablet		2 Tablets	4 Tablets	16 Tablets	20 Tablets	80 Tablets
40 g Tablet	1.44 oz. Tablet				2 Tablet		10 Tablets
50 g Sachet	1.8 oz. Sachet					2 Sachet	8 Sachets
500 g Shaker Bottle	17.6 oz. Shaker Bottle		2 tsp.	4 tsp.	16 tsp. (1/3 cup)	20 tsp.	1-2/3 cups
5 kg Bucket	176 oz. Bucket		2 tsp.	4 tsp.	16 tsp. (1/3 cup)	20 tsp.	1-2/3 cups
		3% Use-Diluted Solution					
Metric	Standard	170 ml. (5.75 oz.)	16 oz. (Pint)	32 oz. (Quart)	128 oz. (Gallon)	160 oz. (5 Quarts)	640 oz. (5 Gallons)
5 g Tablet	0.18 oz. Tablet	1 Tablet	3 Tablets	6 Tablets	24 Tablets	30 Tablets	120 Tablets
40 g Tablet	1.44 oz. Tablet				3 Tablet		15 Tablets
50 g Sachet	1.8 oz. Sachet					3 Sachets	12 Sachets
500 g Shaker Bottle	17.6 oz. Shaker Bottle		1 Tbsp.	2 Tbsp.	0.5 cups	10 Tbsp.	2 - ½ cups
5 kg Bucket	176 oz. Bucket		1 Tbsp.	2 Tbsp.	0.5 cups	10 Tbsp.	2 – ½ cups

[tsp=teaspoon] [Tbsp=tablespoon]

{Dilution table is optional. Full table or specific sections may appear on applicable labels}

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#### {Optional pictograms for making an in-use solution, using select volumes from the dilution chart.}

[How to make a ready-to-use Rely+On MDC Disinfectant Solution]

{32 oz of solution from powder instructions, 1:100 dilution}



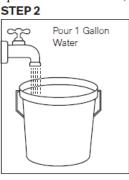


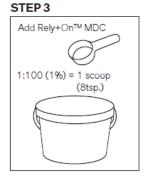




{1 Gallon of solution from powder instructions, 1:100 dilution }









{32 oz of solution from tablet instructions, 1:100 dilution }



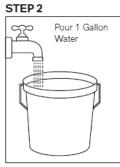


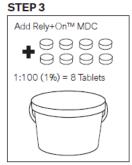




{1 Gallon of solution from tablet instructions, 1:100 dilution }









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Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

#### PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER: Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective clothing and rubber gloves. Wear goggles, face shield, or safety glasses. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement does not refer to 1% in- use solution.

#### **Environmental Hazards**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

{ Effluent discharge statement to be included for package sizes of greater than or equal 5 gallons (liquid) or 50 pounds (solid, dry weight), in accordance with PR Notice 95-1.}

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Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

#### **PESTICIDE STORAGE:**

<u>For pails, jugs, bottles:</u> Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. [Retain desiccant canister with product during storage.] Do not mix this product with other chemicals.

**For [sachet] [pouch] [packet] [bag]:** Store in cool dry place. Keep out of reach of children. [Retain desiccant canister with product during storage.] Do not mix this product with other chemicals.

**<u>IFor spray bottle with in-use solution</u>**: Store in a cool dry place. Keep out of reach of children. Do not mix this product with other chemicals.]

**PESTICIDE DISPOSAL:** Pesticide wastes may be hazardous. [Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.]<sup>{1}</sup> [-refer to product [leaflet] [insert] [booklet] for pesticide disposal instructions]

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. [Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.] [-refer to product [leaflet] [insert] [booklet] for container disposal instructions]

{\langle^1}Note to reviewer: When the size of container prohibits fitting full statement on the container, the text in brackets denoted in [...] \langle^1 above will be replaced with the below statement in red:

[-refer to product [leaflet] [insert] [booklet] for pesticide disposal instructions]

Please note this will only occur when the full statement (denoted in  $[...]^{I}$ ) instead appears on additional labeling accompanying or included with each container of product.}

 $\{^2Note\ to\ reviewer:\ When\ the\ size\ of\ container\ prohibits\ fitting\ full\ statement\ on\ the\ container,\ the\ text\ in\ brackets\ denoted\ in\ [...\ ]^2above\ will\ be\ replaced\ with\ the\ below\ statement\ in\ red:$ 

[-refer to product [leaflet] [insert] [booklet] for pesticide disposal instructions]

Please note this will only occur when the full statement (denoted in  $[...]^2$ ) instead appears on additional labeling accompanying or included with each container of product.}

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TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

### **{DISINFECTANT CLAIMS}**

[One step cleaner/disinfectant\*]

[Cleans and disinfects in one step\*]

[Multipurpose disinfectant cleaner for use on inanimate hard non-porous surfaces]

[Will effectively clean and disinfect when used as directed]

[Hospital Disinfectant]

[Broad Spectrum Disinfectant]

[Effective against Hepatitis A Virus (HAV)]

[Kills Hepatitis A Virus (HAV)]

[Effective against Hepatitis B Virus (HBV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]

[Kills Hepatitis B Virus (HBV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]

[Effective against Hepatitis C Virus (HCV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]

[Kills Hepatitis C Virus (HCV) on pre-cleaned environmental surfaces previously soiled with blood or body fluids]

[Effective against Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on precleaned environmental surfaces/objects previously soiled with blood or body fluids]. [Kills Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus [and HIV-1] on

precleaned environmental surfaces previously soiled with blood or body fluids].

[Effective against Avian Influenza Virus]

[Kills Avian Influenza Virus]

[Effective against both Human and Avian Influenza Virus]

[Kills [more than] 99.9% [bacterial] germs and viruses\*\* (Helicobacter pylori, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella enterica, Pseudomonas aeruginosa, Staphylococcus aureus, and Staphylococcus epidermidis)]

- \* A pre-cleaning step is necessary for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human immunodeficiency Virus (HIV-l) (AIDS virus).
- \*\*Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and HIV (Human immunodeficiency Virus (HIV-l) (AIDS virus).

[Kills Hepatitis B and HIV (Human Immunodeficiency Virus (HIV-1) (AIDS virus) on precleaned environmental surfaces previously soiled with blood or body fluids ] [Kills Hepatitis A Virus, Hepatitis B Virus, [and] Hepatitis C Virus on pre-cleaned environmental surfaces previously soiled with blood or body fluids]

[Virucidal], [Bactericidal], [Germicidal], [Fungicidal]

[Kills bacteria and viruses\* [important to First Responders]: \* Hepatitis A (Hepatitis A Virus), Hepatitis B (Hepatitis B Virus), Hepatitis C (Hepatitis C Virus), HIV (Human Immunodeficiency Virus (HIV-l) (AIDS virus) Kills Pandemic 2009 H1N1 influenza A virus]

- [Disinfects respirators]
- [For disinfecting respirators]

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

- [Sanitizes CPR manikins between use]
- [Efficacious against prevalent hospital pathogens such as MRSA, VRE, RSV]
- [Efficacious against prevalent foodborne pathogens such as Hepatitis A Virus and E. coli O157:H7]

Effective against [Norovirus (Norwalk-like viruses)] [MRSA], [VRE], [RSV], [Influenza virus], [Avian Influenza Virus [(H3N2)], [Swine Influenza A (H1N1) Virus] [Pandemic 2009 H1N1 influenza A virus]

• [Use one tablet per pint of water to make a 1% solution]

#### **<u>{ADDITIONAL MARKETING CLAIMS}</u>**

[Will not harm most surfaces upon incidental contact]

[Will not harm most hard non-porous surfaces]

[Compatible with most surfaces upon incidental contact]

[Compatible with most hard non-porous surfaces]

[Non-damaging to most surfaces upon incidental contact]

[Non-damaging to most hard non-porous surfaces]

[Safe for most hard non-porous surfaces]

[Pleasant citrus scent]

[Does not compromise the integrity of turnout gear (i.e. Treated Cotton, Aramid fiber, Indura® Ultra-Soft®, PBI, Kevlar®, Lenzing FR®, Tychem®, Polyethylene film coated, Saranex 23P film coated, Sparkguard®, Nomex®, Neoprene]

[Compliant with OSHA bloodborne pathogen standard]

[Meets NFPA 1581 guidelines]

[Use powder to absorb spills and solution to disinfect]

[NSF listed]

[Has NSF listing (D1)]

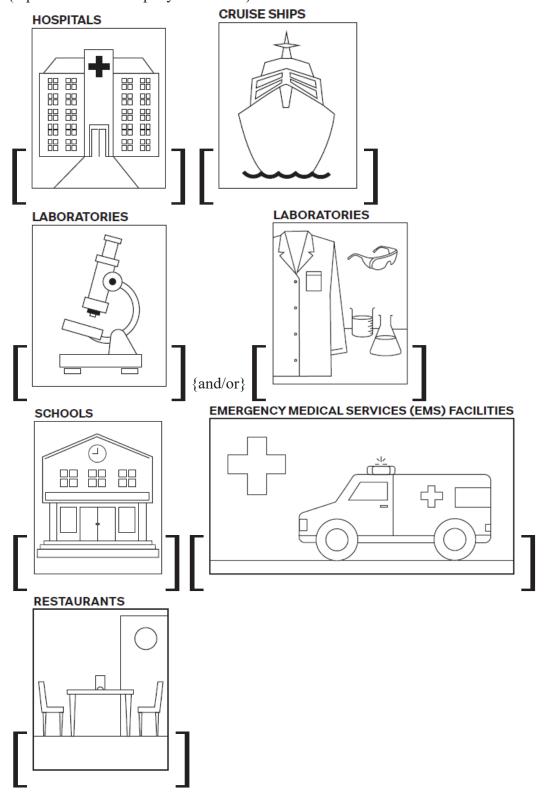
[Fragrance Free]

[No dyes or fragrances added]

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

[Rely+On MDC in-use solutions can be used for disinfection of] [Hospitals] [Cruise Ships] [Laboratories] [Schools] [Emergency Medical Services (EMS) Facilities] [Restaurants]] {Opt. Icons to accompany above text}



TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

{Optional company logo-may appear in color, black only, or grey scale}





{Optional additional logos and/or symbols}



{ NSF logo on back or side panel only, may appear in color or black and white/grey scale}









{ pictograms for optional use with tableted product}

TEXT IN {BRACES} ARE COMMENTS TO REVIEWER

Alternate Brand Name: [Rely+On<sup>TM</sup> Virkon<sup>TM</sup>]

#### {Emerging Pathogen Language}

[This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- -Enveloped Viruses
- -Large non-enveloped viruses
- -Small non-enveloped viruses

For an emerging viral pathogen that is a/an	follow directions for use for the following organisms on the label:			
	Hepatitis A Virus (FRhK-4 cell) (HAV)			
Enveloped Virus	Feline Calicivirus ATCC VR-782 (Surrogate for Norovirus)			
Large, non-enveloped	Hepatitis A Virus (FRhK-4 cell) (HAV)			
virus	Feline Calicivirus ATCC VR-782 (Surrogate for Norovirus)			
Small, non-enveloped	Hepatitis A Virus (FRhK-4 cell) (HAV)			
virus	Feline Calicivirus ATCC VR-782 (Surrogate for Norovirus)			

[Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, Rely+On<sup>TM</sup> Multipurpose Disinfectant Cleaner can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.]

[[Name of illness/outbreak] is caused by [name of emerging virus]. Rely+On<sup>TM</sup> Multipurpose
Disinfectant Cleaner kills similar viruses and therefore can be used against [name of emerging
virus] when used in accordance with the directions for use against [name of supporting virus(es)]
on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for
additional information.]

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